

Pharmaceutical Product Development: Intranasal Scopolamine (INSCOP) Metered Dose Spray

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Motion sickness (MS) has been a problem associated with space flight, the modern military and commercial air and water transportation for many years. Clinical studies have shown that scopolamine is the most effective medication for the prevention of motion sickness (Dornhoffer et al, 2004); however, the two most common methods of administration (transdermal and oral) have performance limitations that compromise its utility. Intranasal administration offers a noninvasive treatment modality, and has been shown to counter many of the problems associated with oral and transdermal administration. With the elimination of the first pass effect by the liver, intranasal delivery achieves higher and more reliable bioavailability than an equivalent oral dose. This allows for the potential of enhanced efficacy at a reduced dose, thus minimizing the occurrence of untoward side effects. An Intranasal scopolamine (INSCOP) gel formulation was prepared and tested in four ground-based clinical trials under an active Investigational New Drug (IND) application with the Food and Drug Administration (FDA). Although there were early indicators that the intranasal gel formulation was effective, there were aspects of formulation viscosity and the delivery system that were less desirable. The INSCOP gel formulation has since been reformulated into an aqueous spray dosage form packaged in a precise, metered dose delivery system; thereby enhancing dose uniformity, increased user satisfaction and palatability, and a potentially more rapid onset of action. Recent reports of new therapeutic indications for scopolamine has prompted a wide spread interest in new scopolamine dosage forms. The novel dosage form and delivery system of INSCOP spray shows promise as an effective treatment for motion sickness targeted at the armed forces, spaceflight, and commercial sea, air, and space travel markets, as well as prospective psychotherapy for mental and emotional disorders.